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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/733,511	10/733,511 12/11/2003		Jennifer Zhao	P-11597.00	9218		
27581	7590	03/01/2006		EXAM	EXAMINER		
MEDTRO	-		KAHELIN, MICHAEL WILLIAM				
710 MEDTI MINNEAPO		NRK I 55432-9924	ART UNIT	PAPER NUMBER			
			3762				

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application I	No.	Applicant(s)					
	Office Astion Comments	10/733,511		ZHAO ET AL.					
	Office Action Summary	Examiner		Art Unit					
		Michael Kahe		3762					
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status									
1) 🏹	Responsive to communication(s) filed on	11 December 2003	}. ·						
•	·	This action is non-							
,—	Since this application is in condition for al			secution as to the	e merits is				
,	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims								
·		otion							
	4) Claim(s) 1-18 is/are pending in the application.								
	4a) Of the above claim(s) is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.									
•	6)⊠ Claim(s) <u>1-18</u> is/are rejected. 7)□ Claim(s) is/are objected to.								
•	Claim(s) are subject to restriction a	and/or election regu	irement						
·			om.						
Applicati	on Papers								
9) The specification is objected to by the Examiner.									
10)⊠ The drawing(s) filed on <u>11 December 2003</u> is/are: a)⊠ accepted or b)☐ objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority (under 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
	☐ All b)☐ Some * c)☐ None of:								
	1. Certified copies of the priority docu	ments have been r	eceived.						
	2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).									
* See the attached detailed Office action for a list of the certified copies not received.									
Attachmen	it(s)								
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)									
	2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152)								
	mation Disclosure Statement(s) (PTO-1449 or PTO/ er No(s)/Mail Date <u>05182005</u> .	6)	<u> </u>	P.F. 122 112 11 (V. V.	•				

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-3, 5, 15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shipko (US 4,316,471 hereinafter "Shipko").
- 3. In regards to claim 1, Shipko discloses an implantable device (19) having a header (41) and couples a lead via a tool (87). The connector header has a header bore (unlabelled cavity of 55), a header grommet aperture with a sidewall (41 at 57), and a connector block (45) with a threaded bore (unlabelled cavity of 45) aligned with the grommet aperture (Fig. 3) adapted to receive a medical lead (51). The grommet (65) is formed of an elastomer (col. 1, line 67). Shipko further discloses that the setscrew body (71) has a socket (83) and is disposed between the grommet (65) and connector block (45) (See Fig. 3, portion of setscrew between 65 and 45), the setscrew has a thread mating with the connector block (Fig. 3), the socket head (75) has a head diameter exceeding the bore diameter (Fig. 3), and the socket head is engaged by a tool inserted through the grommet (Fig. 3, 65) to tighten or loosen the setscrew and the head diameter prevents advancement of the setscrew through the bore (Fig. 3).

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4. In regards to claims 2 and 18, the setscrew is rotatable by a setscrew tool inserted through the grommet (as in Fig. 3) until the setscrew is retracted into frictional engagement with the grommet (65), which stabilizes the setscrew (as in Fig. 4).

- 5. In regards to claims 3 and 17, the header has a retention space (unlabelled voids in Fig. 4) for receiving the setscrew body when in the retracted position.
- 6. In regards to claims 5 and 15, the socket head comprises a plastic (col. 4, line 4) ring (81) molded around a portion of the setscrew body (73).

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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tool.

9. Claims 4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Jackson (US 6,056,753 hereinafter "Jackson"). Shipko discloses the essential elements of the claimed invention except for a setscrew head that is formed with a funnel-shaped opening without a sharp cutting edge. Jackson teaches of a setscrew with a funnel-shaped opening without a sharp cutting edge (col. 7, line 5) to facilitate insertion of a tool. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Shipko's invention with a funnel-shaped opening without a sharp cutting edge to facilitate insertion of a

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- 10. Alternatively, Claims 4, 9, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken (US 5,509,928 hereinafter "Acken"). Shipko discloses the essential elements of the claimed invention except for a setscrew head that is formed with a funnel-shaped opening without a sharp cutting edge. Acken teaches of a setscrew head that is "formed with" (i.e. all components are formed together) a funnel shaped opening (80) that guides a tool (inherent) and provides space accommodating displaced elastomer material (col. 4, line 65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Shipko's invention with a setscrew head that is "formed with" a funnel shaped opening that guides a tool and provides space accommodating displaced elastomer material.
- 11. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Fischer (US 791,548 hereinafter "Fischer"). Shipko discloses the

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essential features of the claimed invention except for a socket that extends for substantially the full length of the setscrew body. Fischer teaches of a setscrew with a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew (line 31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shipko's invention by providing a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew.

- 12. Claims 7, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken. Shipko discloses the essential features of the claimed invention, including a sealing mechanism, but does not disclose a self-sealing passage between the inner and outer grommet walls. Acken teaches of a grommet with a self-sealing passage between the inner and outer grommet walls (Figs. 4 and 5) to provide an additional level of fluid sealing from the electrical contacts. Therefore, it would have been obvious to modify Shipko's invention by providing a self-sealing passage between the inner and outer grommet walls to provide an additional level of fluid sealing from the electrical contacts.
- 13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken, as applied to claim 7 above, and further in view of Jackson. The modified invention of Shipko discloses the essential elements of the claimed invention except for a setscrew head that is formed with a funnel-shaped opening without a sharp cutting edge. Jackson teaches of a setscrew with a funnel-shaped opening without a

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sharp cutting edge (col. 7, line 5) to facilitate insertion of a tool. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Shipko's invention with a funnel-shaped opening without a sharp cutting edge to facilitate insertion of a tool.

- 14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken, as applied to claim 7 above, and further in view of Fischer. The modified invention of Shipko discloses the essential features of the claimed invention except for a socket that extends for substantially the full length of the setscrew body. Fischer teaches of a setscrew with a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew (line 31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shipko's invention by providing a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew.
- 15. Claim14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shipko in view of Acken or Jackson, as applied to claim 12 above, and further in view of Fischer. The modified invention of Shipko discloses the essential features of the claimed invention except for a socket that extends for substantially the full length of the setscrew body. Fischer teaches of a setscrew with a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew (line 31). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shipko's invention by

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providing a socket that extends for substantially the full length of the setscrew body to equalize strain by applying force to the whole length of the setscrew.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-9, 12, and 15-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31 of copending Application No. 10/732,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are more narrow and meet the limitations of the broader claims of this application.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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